Bipartisan Group of Members Introduces â€œPromoting Innovation and Access to Life-Saving Medicines Actâ€•

Reps. Henry A. Waxman, Frank Pallone, Nathan Deal, and Jo Ann Emerson introduced H.R. 1427, the “Promoting Innovation and Access to Life-Saving Medicine Act,” a bipartisan bill to allow the Food and Drug Administration to approve affordable copies of biotech drugs. Biotech drugs, while often life-saving, are the fastest growing and most expensive components of the nation’s prescription drug bill. Many of them cost tens of thousands of dollars a year — prices that put them out of reach of patients and impose an unsustainable burden on employers, insurers, and the federal government.

FDA currently lacks clear authority to approve generic versions of these products, allowing companies to charge monopoly prices even after all patents have expired. Introducing fair competition for biotech drugs is essential to keep these life-saving treatments affordable. Today’s bill gives FDA authority to ensure that any approved copy of a biotech drug is just as safe and effective as the original product, and provides the makers of new biotech drugs ample incentives for continued innovation. The Promoting Innovation and Access to Life-Saving Medicine Act is consistent with the legislation described in the President’s proposed budget.

“I believe this bill will lead to healthy competition and long-term savings for patients and payers, and will preserve innovation in the biotech marketplace,” said Rep. Waxman, Chairman of the House Energy and Commerce Committee. “Above all, this bill guarantees that FDA has the scientific discretion to hold these drugs to the same high standard to which the original products are held. The only way we can succeed in establishing robust competition for biotech drugs is with biosimilar drugs that doctors and patients know they can count on.”

“By creating a pathway for generic biologics, we hope to increase access to these life-saving drugs, lower prices and spur innovation,” said Rep. Pallone. “This bipartisan legislation empowers the FDA with the flexibility and authority it needs to ensure that generic products are safe and effective. With this legislation, we are ending the monopoly on biologics, and I look forward to working with my colleagues to pass it quickly.”

“While biologics are highly effective medications in the treatment of a host of debilitating and life-threatening medical conditions, biologic drugs often cost on average 22 times more per daily dose than chemical medications, the most expensive of which costs well over $100,000 per year,” said Rep. Deal. “It is expected approximately 50% of all drugs approved in 2010 will be a biopharmaceutical, a projection which only underscores the need for this legislation as the strain on state and federal governments grows. As the pharmaceutical market is further saturated by biologics, mechanisms must be put into place to promote competition and continued innovation. Generic and brand name companies alike are now planting their seeds in the emerging follow-on biologic market and Congress should make every effort to support these efforts with the best interest of patients in mind. This sensible, consumer-focused legislation represents a dramatic first step in passing legislation to establish an approval and regulatory pathway for biologic products and I am pleased to join Chairman Waxman and Chairman Pallone in co-sponsoring the Promoting Innovation and Access to Life-Saving Medicine Act.”

“I’m pleased to be a part of a commonsense effort at this bipartisan bill to bring generic versions of name-brand biologic medicines to market,” said Rep. Emerson. “Across the country, Americans who cannot afford name-brand biologics have been left with no alternatives to their high prices for decades. This bill would create access to affordable generic versions of their prescriptions during an especially difficult economic time for many American families and senior citizens on fixed incomes. Generic medicines are widely relied upon in our country, and

consumers deserve generic versions of biologics, which are some of the most expensive drugs on the market.”

This bill has unusually broad support from a wide spectrum of affected groups, including businesses, payers, patient groups, consumer groups, and unions. It has been endorsed by, among others, the Consumers Union, AARP, the National Organization of Rare Disorders, the Coalition for a Competitive Pharmaceutical Market, General Motors, Express Scripts, Inc, the National Business Group on Health, the AFL-CIO, and the SEIU.

Sens. Schumer, Collins, Brown, and Vitter are expected to introduce a bipartisan companion bill in the Senate in the near future.

Documents

- H.R. 1427, the "Promoting Innovation and Access to Life-Saving Medicine Act"

- Summary of H.R. 1427

- Detailed Summary of H.R. 1427

- Letters in support of H.R. 1427